UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,261	01/16/2004	Gerhard Moersdorf	06478.1497	5706

22852 7590 12/02/2008

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/758,261	MOERSDORF ET AL.	
	Examiner	Art Unit	
	ANDREW M. GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-35* is/are pending in the application.

4a) Of the above claim(s) *24-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/17/2008 has been entered.

Acknowledgments

1. This office action is in response to the reply filed on 10/17/2008.

2. In the reply, the Applicant amended claims 1, 3, 10, 13, and 23.

3. Claims 24-35 were previously withdrawn.

4. Thus, claims 1-4, 6-23 are pending for examination.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4, 6-11, 13, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon (5879336) in view of Kulle (4346704) in further view of Beauvais et al (5876379).

7. Brinon discloses a sterile sheath (13; Fig 4) comprising: a sealed casing (13; wherein Webster's defines a seal as "something that confirms, ratifies, or makes secure" and "a closure that must be broken to be opened" and thus, the casing (13) is sealed by the cover (20) such that the cartridge is secured inside the casing; additionally, see Response to Arguments discussion below) made of plastic, the casing including an output connection piece (13), wherein the output connection piece includes a valve (2, Fig 1-3) whose direction of flow is exclusively from an injection syringe to the exterior, wherein an interior (Fig 1-8) of the sterile sheath is configured to receive the entire injection syringe, and wherein the output connection piece is configured to be connected to the syringe (Fig 3, 11, 10); wherein an outer region (12a) of the output connection piece is configured to receive a medical device, and wherein the medical device is one of a needle, an adapter, a multiport valve, and an infusion bottle (col 2, lns 50-52); wherein the sealable casing is at least partially transparent (col 3, lns 24-28);wherein the valve is one of a non-return valve (2); wherein the output connection piece includes a cone-shaped recess (10, 9; Fig 3) configured to receive a syringe cone of the injection syringe; wherein the output connection piece includes a hollow body (13) configured to receive a cylindrical section of the injection syringe; wherein the hollow body has a cylindrical shape (13; Fig 1-8); wherein the output connection piece includes, on an end opposite from the valve, an annular plate (22); the sealable casing further comprising a pressure pocket (20) configured to connect to the output connection piece; further comprising a sealing element (Fig 1, 6-8) to seal between the output connection piece and the pressure pocket; wherein the output connection piece

includes a section configured as a cone (inner annular projection inside luer lock 12a – Figs 1, 3) to receive a cone-shaped recess of the medical device; wherein the output connection piece and the medical device are connected by means of a swivel closure (12a); wherein the swivel closure is a screw thread (12a).

8. However, Brinon does not expressly disclose wherein the output connection piece includes as least on radial discharge aperture sealable by means of an elastic ring element, wherein the elastic ring element is a tubular ring element, which encloses a portion of the output connection piece.

9. Kulle teaches that it is known to have the output connection piece includes as least on radial discharge aperture sealable by means of an elastic ring element, wherein the elastic ring element is a tubular ring element, which encloses a portion of the output connection piece (48, 40; Fig 2) for the purpose of a one-way valve with low residual volume so that critical medications may be administered in precise quantities with less waste while also providing higher flow rates at lower pressures (col 2, lns 17-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the uni-directional valve as taught by Brinon with the unidirectional valve being a radial discharge aperture sealable by means of a tubular elastic ring element as taught by Kulle for the purpose of providing a one-way valve with low residual volume so that critical medications may be administered in precise quantities with less waste while also providing higher flow rates at lower pressures (col 2, lns 17-24).

10. However, Brinon in view of Kulle do not expressly disclose the output connection piece having an upper end with a portion extending radially outward from the body and configured to coextend with a flange of an injection syringe, and the radially outward extending portion is an annular plate having an oval aperture.

11. Beauvais et al teaches that it is known to have the output connection piece having (12) an upper end with a portion extending radially outward from the body (18) and configured to coextend with a flange (38) of an injection syringe, and the radially outward extending portion is an annular plate (18) having an oval aperture (38, 18; Figs 1-2) for the purpose of holding the syringe within the outer sleeve and preventing disconnection from the cannula during use (Summary). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the upper end portion as taught by Brinon in view of Kulle with radially outward extending portion with connection to a syringe flange as taught by Beauvais et al for the purpose of holding the syringe within the outer sleeve and preventing disconnection from the cannula during use (Summary).

12. Claim 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Kulle in further view of Beauvais et al. Brinon in view of Kulle in further view of Beauvais et al discloses the invention substantially as claimed except for expressly disclosing the output connection piece being formed by injection molding. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the output connection piece as taught by Brinon in view of Kulle and Beauvais

et al with an output piece made by injection molding since it was well known in the art that injection molding is used to provide rigid plastic parts for medical devices.

13. Claims 14-16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Kulle in further view of Beauvais et al. Brinon in view of Kulle and Beauvais et al discloses the invention substantially as claimed except for expressly disclosing wherein the pressure pocket is formed by injection molding, by a dipping method, or by means of extrusion-blow molding. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the pressure pocket formed by injection molding, by a dipping method, or by means of extrusion-blow molding because the Applicant has not disclosed that having the pressure pocket formed by injection molding, by a dipping method, or by means of extrusion-blow molding provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the pressure pockets of Brinon in view of Kulle and Beauvais et al because the pressure pockets perform substantially the same function in substantially the same manner. Furthermore, claims 14-16 are directed to a product by process and it has been held that the patentability of the product does not depend on its method of production (see MPEP 2112.02). Therefore, it would have been an obvious matter of design choice to modify Brinon in view of Kulle and Beauvais et al to obtain the invention as specified in claims 14-16.

14. Claim 17-18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Kulle in further view of Beauvais et al and in additional view of Riuli

(4713060). Brinon in view of Kulle in further view of Beauvais et al additionally discloses wherein the shoulder piece includes a snap-in lug (14) configured to engage a snap-in lug (18) on an annular plate of the output connection piece. However, Brinon in view of Kulle and in further view of Beauvais et al does not expressly disclose wherein the pressure pocket includes a shoulder film-like plastic hood. Riuli teaches that it is known to have wherein the pressure pocket includes a shoulder film-like plastic hood (40) for the purpose of providing a flexible cover flexible enough to allow movement of the plunger while acting as a barrier for helping to blow the transfer of fluid and particulate matter between the chamber and the environment (Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pressure pocket as taught by Brinon in view of Kulle and Beauvais et al with the film-like plastic as taught by Riuli for the purpose of providing a flexible cover flexible enough to allow movement of the plunger while acting as a barrier for helping to blow the transfer of fluid and particulate matter between the chamber and the environment (Abstract).

15. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Riuli, in further view of Beauvais et al, and in further view of Kulle. Brinon and Riuli and Beauvais et al disclose the invention substantially as claimed except for wherein the output connection piece further includes at least one radial discharge aperture sealable by means of an elastic ring element. Kulle teaches that it is known to have at least one radial discharge aperture (48) sealable by means of an elastic ring element (40) for the purpose of providing uni-directional flow with a low residual valve

size (see Disclosure of Invention). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the one-way valve as taught by Brinon and Riuli and Beauvais et al with the radial aperture and elastic ring valve as taught by Kulle for the purpose of providing uni-directional flow with a low residual valve size (see Disclosure of Invention).

Response to Arguments

2. Applicant's arguments with respect to claims 1-4, 6-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 Form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767